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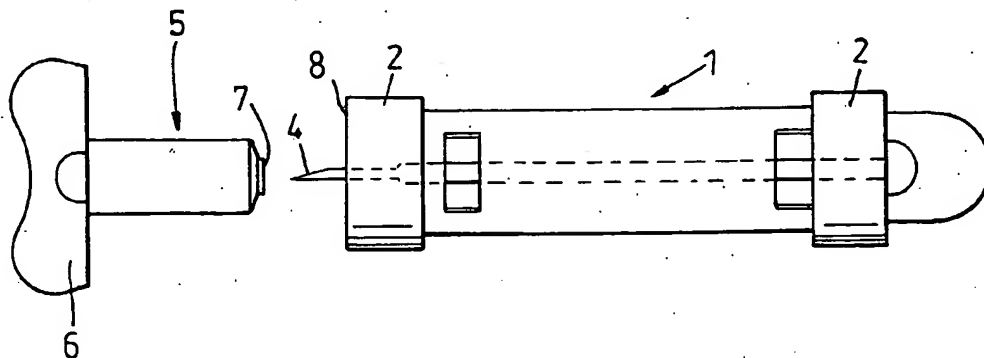
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(54) Title: **LANCET FOR SKIN PRICKERS**



(57) Abstract: A lancet for a skin pricker has needle (3) encased, apart from its tip (4), in a plastics body (1). That tip may initially be encased in a breakaway cap (5) integrally moulded with the body (1). The needle (3) is made from a cylindrical blank reduced to a smaller diameter near one end, whose free extremity is sharpened to form the tip (4). The transitional step or shoulder (11) between different diameter portions (9, 10) is within the plastics body (1), preventing the needle (3) moving forwards relative to that body. The reduction can be achieved by centreless cylindrical grinding, rolling or turning.

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LANCET FOR SKIN PRICKERS

This invention relates to lancets for skin prickers. These draw a small drop of blood for analysis, and they are widely used by diabetics, for example, who need to know
5 their sugar level.

One of the intricate and complex tasks faced in manufacturing such devices is the precision machining and grinding required to form a point on the needle tip. This typically requires three flats to be ground onto the needle
10 tip. This is exacerbated by the desire to make the cross-section of the needle tip as small as possible to achieve a sharper point and therefore give a less noticeable prick. For an existing design such as that shown in EP-B-0 858 289 the needle blanks are taped up, i.e. attached in a row
15 between two layers of sticky tape, and then ground in several passes to produce a flat at one end of each blank. This portion of reduced cross-sectional area then has a point formed at its tip. However, while this can give a really sharp point, the needle is of small diameter and
20 there are difficulties arising from such lack of size during the moulding processes. It would be easier to precision machine and mould around a more substantial body, especially in high volume manufacture.

According to one aspect of the present invention there
25 is provided a lancet for a skin pricker, the lancet having a needle encased, apart from its tip, in a body of plastics material, the needle being of generally circular cross-

section within the body but with a reduction in diameter before emerging at the tip.

With this construction the diameter of the main body of the needle can be sufficiently large to enhance the rigidity of the lancet main body. It can also facilitate
5 handling of the needle blank during its manufacturing and moulding stages.

The reduction in diameter may either be by an abrupt step or by a tapered shoulder.

Often a breakaway cap will be integrally moulded with the body to encase the needle tip. This is for safety and hygiene, and the cap may also serve as the part which the user manipulates to cock the lancet firing device. When the cap is removed the step or shoulder will prevent any
10 tendency of the needle to shift forwards and expose more tip than intended.
15

The larger diameter portion of the needle preferably has a diameter in the range 0.6 to 1.0 mm, and ideally a diameter of about 0.8 mm (21 gauge). The reduced diameter
20 portion of the needle preferably has a diameter in the range 0.2 to 0.5 mm, and the optimum is likely to be in the range 0.3 to 0.4 mm.

According to another aspect of the present invention there is provided a method of producing a lancet for a skin
25 pricker, the method comprising:

providing a generally cylindrical needle blank,
reducing the diameter of one end portion of the

blank,
forming a point on the free end or tip of said one end
portion, thus creating a needle,
introducing the needle into a mould, and
5 introducing plastics material into said mould to
form a lancet body around the needle apart from its
tip.

The tip may have a breakaway plastics cap moulded
around it in the same operation as the moulding of the
10 body, as mentioned above.

The reduction of said one end portion of the blank may
be by centreless cylindrical grinding, rolling or turning.

Needle blanks of a diameter corresponding to that of
the main body of the finished needle may be supplied to an
15 automated machining or working device, which machines or
works the blank to produce the reduced diameter portion to
form the needle tip. This is achieved without the
laborious process of taping up needle blanks as previously.
Since the part-formed blank (prior to needle tip formation)
20 resulting from this process is still rotationally
symmetric, further handling and manufacture of the needle
and the complete lancet is facilitated.

For a better understanding of the invention, one
embodiment will now be described, by way of example only,
25 with reference to the accompanying drawing, in which:-

Figure 1 is a side view of a lancet in a pre-used
condition;

Figure 2 is another side view of the lancet taken from a direction perpendicular to that of Figure 1;

Figure 3 is a view of the lancet similar to that of Figure 2 but showing the breakaway cap removed,

5 Figure 4 is a cross-section taken on lines iv - iv of Figure 2, and

Figure 5 is a side view of a needle for this lancet.

The lancet has an elongate body 1 of moulded plastics material. As is apparent in Figure 4, the body is of
10 generally rectangular section with two circular collars 2 at opposite ends. Coaxially encased within the body is a needle 3, shown in dotted lines in Figures 3 and 4 and fully in Figure 5, and which projects in a sharp tip 4 at the forward end.

15 The tip 4 is initially encased in a cap 5 which is in the form of a clock key with a transverse head 6. The cap 5 is integrally moulded with the body 1 and connects to it by a neck 7 which is weak enough to be sheared off from the end surface 8 of the body by a twisting action. Such a cap
20 may not always be provided.

The needle has a cylindrical main body portion 9 over most of its length, the remainder being a co-axial needle tip portion 10 at one end of reduced diameter produced by a process such as centreless cylindrical grinding, rolling or
25 turning. The free extremity of this portion 10 is ground to provide the sharp tip 4. In this embodiment the outer diameter of the portion 9 is of the order of 0.8

millimetres (21 gauge) with the diameter of the needle tip portion 10 being of the order of 0.3 to 0.4 millimetres, but the invention is not limited to these dimensions or to similar proportions. It is considered reasonable for the larger diameter to be in the range 0.6 to 1.0 millimetres and the reduced one to be in the range 0.2 to 0.5 millimetres. Between the portions 9 and 10 is a shoulder 11 which is encased in the lancet body to prevent the needle from moving forwardly when the cap is removed. As shown in Figure 5 it is an abrupt step, but it could be a tapered transition.

In one example of the manufacture of the lancet, a supply of needle blanks of the appropriate length but of constant diameter is fed to an automated centreless cylindrical grinding machine which is set up to grind the needle blanks to provide the reduced diameter tip portion 10. These rotationally symmetric intermediate blanks are then supplied to a grinding machine to form the needle point or tip 4 (typically by grinding three flats). The formed needles are then delivered to a moulding machine where they are held within the mould cavity by mould pins (not shown). The body, and cap if provided, is then moulded around the needle in plastics material. Finally, the completed lancet is ejected from the mould.

CLAIMS

1. A lancet for a skin pricker, the lancet having a needle encased, apart from its tip, in a body of plastics material, the needle being of generally circular cross-section within the body but with a reduction in diameter before emerging at the tip.
2. A lancet as claimed in Claim 1, wherein the reduction in diameter is by an abrupt step.
3. A lancet as claimed in Claim 1, wherein the reduction in diameter is by a tapered shoulder.
4. A lancet as claimed in Claim 1, 2 or 3, wherein a breakaway cap is integrally moulded with the body to encase the needle tip.
5. A lancet as claimed in any preceding claim, wherein the larger diameter portion of the needle has a diameter in the range 0.6 to 1.0 mm.
6. A lancet as claimed in Claim 5, wherein the larger diameter portion of the needle has a diameter of 0.8 mm.
7. A lancet as claimed in any preceding claim, wherein the reduced diameter portion of the needle has a diameter in the range 0.2 to 0.5 mm.
8. A lancet as claimed in Claim 7, wherein the reduced diameter portion of the needle has a diameter in the range 0.3 to 0.4 mm.
9. A method of producing a lancet for a skin pricker, the method comprising:
providing a generally cylindrical needle blank,

reducing the diameter of one end portion of the
blank,

forming a point on the free end or tip of
said one end portion, thus creating a needle,

5 introducing the needle into a mould, and
introducing plastics material into said mould to
form a lancet body around the needle apart from
its tip.

10 10. A method as claimed in Claim 9, wherein the reduction
of said one end portion of the blank is by cylindrical
grinding.

11. A method as claimed in Claim 9, wherein the reduction
of said one end portion of the blank is by rolling.

15 12. A method as claimed in Claim 9, wherein the reduction
of said one end portion of the blank is by turning.

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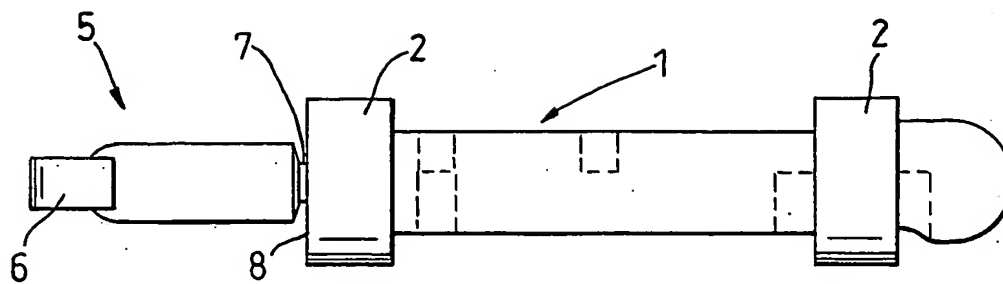


Fig. 1

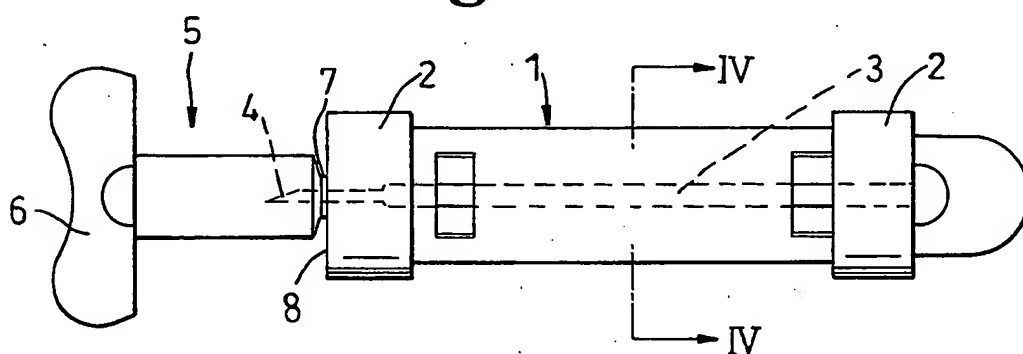


Fig. 2

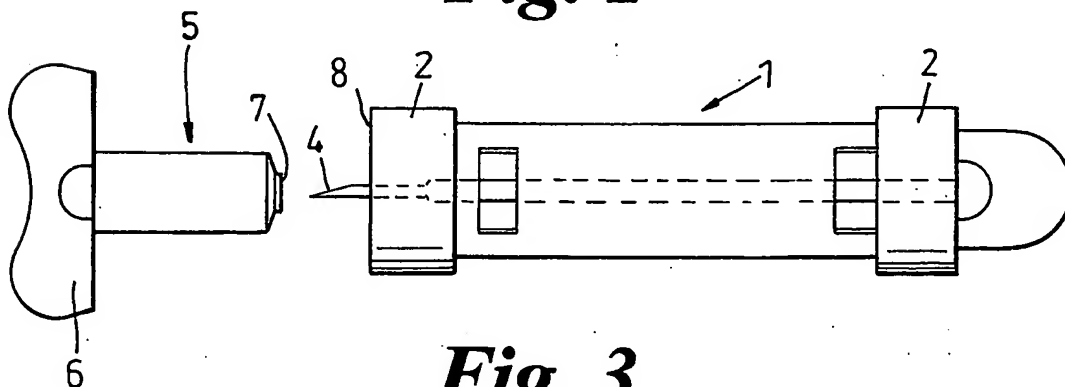


Fig. 3

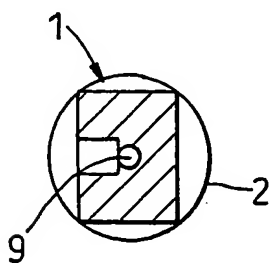


Fig. 4

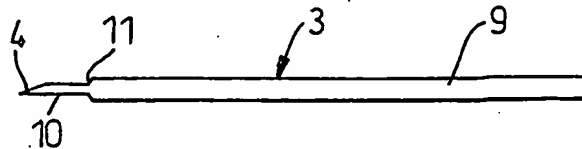


Fig. 5

INTERNATIONAL SEARCH REPORT

Intern plication No
PCT/GB 01/05433

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/15

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 02189 A (OWEN MUMFORD LTD ;MARSHALL JEREMY (GB); CROSSMAN DAVID DANVERS (GB) 1 February 1996 (1996-02-01) cited in the application page 5, line 14-19; claims 9-11; figure 4	1,2,4,9
Y		5
Y	EP 0 589 186 A (APLS CO LTD) 30 March 1994 (1994-03-30) column 8, line 29-46 column 10, line 3-30 figures 3,4,11	5

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9602189	A	01-02-1996	DE 69517709 D1	03-08-2000
			DE 69517709 T2	22-02-2001
			EP 0858289 A1	19-08-1998
			ES 2149998 T3	16-11-2000
			WO 9602189 A1	01-02-1996
			JP 10502557 T	10-03-1998
			US 5913868 A	22-06-1999
EP 0589186	A	30-03-1994	AU 4441493 A	03-03-1994
			CA 2104269 A1	01-03-1994
			DE 69326930 D1	09-12-1999
			DK 589186 T3	03-01-2000
			EP 0589186 A1	30-03-1994
			ES 2137212 T3	16-12-1999
			KR 137072 Y1	20-03-1999
			US 5385571 A	31-01-1995

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